Course in English language

GDP 3

GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

06 September 2023, Basel

Highlights

- Legal Bases for the Distribution of Medicinal Products
- Tasks and Responsibilities
- Distribution to, from and out of Switzerland
- Practical Aspects of Storage and Transportation
- Liability and Indemnification

Supported by the European GDP Association

GDP ASSOCIATION

Speakers

Dr Ina Bach
Dr Bach

Dr Johannes Fröhlich
Akroswiss

Dr Felix Kesselring
Bratschi

Dr Remo Studer
Galexis

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Objectives

- Learn and discuss how to manage your distribution activities GDP-compliant.
- Exchange opinions and convey possible solutions to problems addressed in case studies.
- Benefit from the speakers' experience in industry, authority and legal advice.

Background

Quality requirements for medicines do not end after production and packaging. Medicines and APIs are often shipped over long distances and different climate zones and stored in various warehouses. Once the WHO has taken the lead with its guidelines „Good Storage Practices for Pharmaceuticals" (2003) and „Good Distribution Practices for Pharmaceutical Products" (2010), more and more compliance with good storage, transportation and distribution practice was emphasised worldwide. Another milestone were the EU-GDP guidelines from 2013 with a lot of intensified demands.

For quite a while it was rather unclear how these guidelines are applicable in the non-EU country Switzerland. Under the Agreement of 21 June 1999 between the Swiss Confederation and the European Community (**Mutual Recognition Agreement, MRA**), Switzerland obliged to comply with the EU-GMP regulation. However, GDP was not covered.

Since 1 July 2015, the EU GDP guidelines do also apply for Switzerland (final implementation on January 1st 2016). This was realised through an adaptation of Annex 2 of Ordinance on Establ ishmentLicences(Arzneimittel-Bewilligungsverordnung - **AMBV** or Ordonnance sur les autorisations dans le domaine des médicaments - **OAMéd**).

On 1 January 2019, the revised **Therapeutic Products Act (HMG 2)** and the majority of the revised implementing ordinances **(Therapeutic Products Ordinance Package IV)** came into force - with some interesting changes.

Various transitional provisions for licenses issued under the old legislation are defined. However, for all new/renewed applications, the new legislation will apply in its entirety.

Target Audience

This course has been designed for employees, specialists and managers from storage, transportation and distribution as well as their colleagues from quality control, quality assurance and production, which are involved in the various processes of drug logistics.

Programme

Legal Bases for the Distribution of Medicinal Products

- Legal basis in Switzerland including EU regulations
- The Ordinance on Establishment Licences OEL (AMBV, OAMéd)
- The revised Therapeutic Products Act (HMG 2): relevant changes
- GMP/GDP Interface
- Working with contractors

Practical Implementation in Switzerland

- The GDP Inspection: what do inspectorates expect and how to prepare
- Wholesaler vs. Pre-Wholesaler: interfaces and delimitation
- Transport at storage conditions: best practices
- Case Study: transport validation

Tasks and Responsibilities

- Requirements and due diligence for the Responsible Person according Art. 9 and 13 of the Ordinance on Establishment Licences
- Storage and distribution: current expectations
- Cross-border Distribution: Requirements for Import and Export
- Requirements for specific products
- Qualification of suppliers and recipients
- Senior Management
- Responsible Person

Liability

- Principles of liability
- Who is liable?
- Potential sanctions
- Examples from the real life, case law

Storage and Transport: Practical Aspects (Interactive Session)

a) Warehouse
- Requirements
- Qualification
- Mapping
- Hygiene
- Documentation

b) Transport
- Transport qualification/ validation
- Transport at ambient conditions: expectations and control
- Deviation management
- Cool and cold chain
- Risk Analysis
- Training

GDP ASSOCIATION

The European GDP Association

The European GDP Association aims to support Pharmaceutical Industry, Authorities and Logistic Providers with regard to the implementation of Good Distribution Practice.

It represents all stakeholders e.g. from Pharmaceutical Industry, Authorities and Logistic Providers and supports all members and stakeholders by providing them information and support in the implementation of GDP.

The Association is a not for profit organisation under the umbrella of the ECA Foundation. Membership is fee to all individuals involved in Good Distribution Practice (currently more than 2.000 members).

www.good-distribution-practice-group.org

Dr Ina Bach
Dr. Bach AG

Dr Ina Bach is General Manager of Dr. Bach AG in St.Gallen. Dr Bach was a GMP- and GDP-Inspector at the RHI (Regionales Heilmittelinspektorat der Nordwestschweiz) and point of contact for foreign inspections by FDA, ANVISA and EMA.

Dr Johannes Fröhlich
Akroswiss AG

Dr Johannes M. Fröhlich is Pharmacist and General Manager at Akroswiss AG. He also works as a consultant in the area of GDP an das Responsible Person (RP). He holds a lectureship at the pharmaceutical institute of the ETH-Zürich.

Dr Remo Studer
Galexis AG

Dr Remo Studer Head of Quality Management and Responsible Person at Galexis AG, a wholesaler and part of Galenica.

Dr Felix Kesselring, LL.M. (LSE)
Bratschi AG

Dr Felix Kesselring studied at the universities of Zurich and Strasbourg. He received an LL.M. in Public Law from the London School of Economics and Political Science (LSE) and a doctorate (Dr. iur.) from the University of Basel. Felix Kesselring has been working as a lawyer since 2009. He holds a lectureship at the ETH-Zürich.

Participants' comments:

"Very good course"
Igor Todorcevski, Alkaloidpharm SA

"Very useful presentations! Thank you!"
Dr. Thorsten Dedecke, Fresenius Medical Care (Schweiz)

Absender

Anmeldung/Bitte vollständig ausfüllen

GDP in Switzerland - Specifics in the Distribution of Medicinal Products and APIs (GDP 3)
06 September 2023, Basel

Titel, Name, Vorname

Abteilung

Firma

Telefon / Fax

E-Mail (bitte angeben)

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Date
Wednesday, 06 September 2023, 9.00h – 17.30h
(Registration and coffee 8.30h – 9.00h)

Venue
Pullman Basel Europe
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On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

Fees
GDP Association Members € 1.090
(equates 1.074 CHF, dated December 2022)
Non-members 1.290 €
(equates 1.270 CHF, dated December 2022)
Relevant for payment is the price in Euro.
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Important Information!
The presentations of this GDP Course will be available for download and your print-out one week before the conference. **Note: there will be no print-outs available during the conference.**

Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive an information form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gdp-navigator.de or www.gmp-navigator.com

Conference language
The official conference language will be English.

Organisation
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